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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,655	05/01/2006	Kazuhiro Machida	0425-1257PUS1	3246
2292 7590 09/15/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
EPFS -SMITH, JANET L				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
09/15/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/577,655

**Applicant(s)**

MACHIDA ET AL.

**Examiner**

Janet L. Epps-Smith

**Art Unit**

1633

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,12 and 14-31 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,12,14-16 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 17-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3-6, 12, and 14-31 are pending.
3. Claims 3, 6, 12, 14-16, and 24-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
4. Claims 1, 4-5 and 17-23 are presently under examination.

#### ***Claim Rejections - 35 USC § 112***

5. The rejection of claims 1, 4-5, and 21-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to applicant's amendment.

#### ***Claim Objections***

6. The objection to claims 17-20 as being dependent upon a rejected base claim, is withdrawn in response to the rejection set forth below.

#### ***Claim Rejections - 35 USC § 102***

7. The rejection of claims 1, 4-5 and 21-23 under 35 U.S.C. 102(b) as being anticipated by Nakajima et al. (WO2003040370A1, in Japanese, see English publication US2005/0084859 A1), is withdrawn in response to Applicant's amendment.

#### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3-6, 12, and 14-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of copending Application No. 11919579. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are

drawn to transformants and isolated DNA, wherein said isolated DNA comprises a DNA encoding a protein having 16-position hydroxylating enzymatic activity which is characterized by the following: (a) a DNA encoding a protein having the enzymatic activity to hydroxylate the 16- position of the macrolide compound 11107B, wherein the DNA is selected from the group consisting of (1) a continuous nucleotide sequence from base 1322 to base 2548 of SEQ ID NO: 1; (2) a continuous nucleotide sequence from base 420 to base 1604 of SEQ ID NO: 4; and a continuous nucleotide sequence from base 172 to base 1383 of SEQ ID NO: 7. The claims of the copending application are drawn generically to a recombinant microorganism (i.e. a transformant) comprising a DNA encoding a protein having the enzymatic activity to hydroxylate the 16-position of the macrolide compound formula (II or 11107B, as set forth in the instant claims), and further wherein said DNA is selected from the group consisting of: (b-1) the continuous nucleotide sequence of nucleotides 1322 to 2548 in the Sequence No. 2; (b-2) the continuous nucleotide sequence of nucleotides 420 to 1604 in the Sequence No. 3; and (b-3) the continuous nucleotide sequence of nucleotides 172 to 1383 in the Sequence No. 4, or a variant thereof. The nucleotide sequences set forth in the copending application are identical to the sequences set forth in the instant claims, particularly: (1) a continuous nucleotide sequence from base 1322 to base 2548 of SEQ ID NO: 1; and (2) a continuous nucleotide sequence from base 420 to base 1604 of SEQ ID NO: 4. The claims of the instant application are encompassed within the broad scope of generic claim 1 of the copending application, and thus anticipates the copending claim. Claim 6 of the copending application differ from the instant claims to the extent that the

instant claims recite the term "transformant" and the copending claims recite "recombinant microorganism." One of ordinary skill in the art would have recognized that these terms read on common subject matter. The transformant comprising the nucleotide sequences mentioned above, anticipate the scope of the copending claims which read on a recombinant microorganism comprising the same DNA molecules.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

11. Claims 1, 3-6, 12, and 14-31 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. In the instant case, it appears that the instant application and copending application 11919579 recite claims directed to common subject matter. However, it is noted that these applications do not share the same inventive entity. The instant application was filed by Inventors: Machida, Aritoku, Tsuchida, and Nakashima. However, the copending application was filed only by the following inventors: Machida and Aritoku. It is requested that Applicants verify the inventors of the subject matter shared between these two copending applications.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633